

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS

)
THIS DOCUMENT RELATES TO:)
)
GOVERNMENT EMPLOYEES)
HOSPITAL ASSOCIATION, and)
DISTRICT COUNCIL 37 HEALTH)
AND SECURITY PLAN TRUST,)
Individually and on behalf of all others)
similarly situated,)
Plaintiffs)
)
v.)
)
SERONO INTERNATIONAL, S.A.,)
SERONO LABORATORIES, INC.,)
SERONO, INC., RJL SYSTEMS, INC.,)
And RUDOLPH J. LIEDTKE,)
Defendants.)

)

**RESPONSE OF THE SERONO DEFENDANTS TO PLAINTIFFS' MOTION TO
REMOVE SPECIFIC ACTION FROM MDL**

The defendants Serono International S.A., Serono Laboratories, Inc., and Serono Inc. (for purposes of this response, "Serono") do not object to having this matter removed from the AWP MDL. However, Serono believes that this action should remain with this Court as C.A. No. 05-CV-11935 (PBS), because this Court has extensive experience with the factual, regulatory, and legal issues involved in the sales and marketing of prescription drugs, and those issues are the heart of this case. Consequently, the best way to achieve judicial economy and serve the interests of justice is to have this case remain in this Court. *See* Local Rule 40(I) (Reassignment and Transfer of Cases).

BACKGROUND

The Plaintiffs' **Factual Background** is nothing more than a summary of the allegations and claims in their Second Amended Complaint, and a characterization of the criminal charges to which one Serono defendant – Serono Laboratories, Inc. – entered a guilty plea on December 15, 2005. Serono disagrees with the allegations and claims in the Second Amended Complaint, and will refute them at the appropriate time. But, there is one issue of potential confusion that must be clarified at this time, and that concerns the criminal plea by Serono Laboratories, Inc.

Contrary to the impression conveyed by the Plaintiffs, Serono Laboratories, Inc. entered a guilty plea – and was sentenced on – two charges of criminal conspiracy. The first was conspiracy to introduce an adulterated medical device into interstate commerce, and the second was conspiracy to offer to pay illegal remuneration. The transcript from the plea hearing before the Sentencing Court clarifies the narrow focus of these charges. With respect to the first charge, Serono Laboratories, Inc. admitted that “in the late 1990’s . . . Serono Labs with R.J.L. introduced the BIA machines that contain[ed] software that was not approved by the FDA.” With respect to the second charge, Serono Laboratories, Inc. admitted that it “and at least one company employee conspired to make payments in the form of a free trip to Cannes, France for physicians.” *See* transcript of sentencing hearing pages 61 through 66 (excerpt attached as Exhibit 1).

In other words, there was very little of substance in the criminal plea and sentencing process that bears upon the issues that must be resolved in this civil action. The hearing was completed in the course of one morning, and there have been no further proceedings before the Sentencing Court.

Turning to the **Procedural Background**, Serono agrees that the Second Amended Complaint is the Plaintiffs' third attempt to plead their claims, agrees that the case in its present

incarnation does not contain an AWP claim, and agrees that this matter should be “unbundled” from the AWP MDL. However, should the Plaintiffs amend their Second Amended Complaint yet again to add AWP claims, Serono will request that the case be placed back into the AWP MDL.

As for the **Reassignment of This Action**, Serono believes that this case should remain in this Court as C.A. No. 05-CV-11935 (PBS) for the following reasons:

- The allegations and claims made against Serono in the Second Amended Complaint are similar in nature and scope¹ to the allegations made by the plaintiffs in In re Neurontin Marketing, Sales Practices, and Products Liability Litigation, (the *Neurontin Action*), which is currently pending before this Court;
- Based upon the pleadings filed thus far, this action and the *Neurontin Action* involve many of the same legal issues;
- Through its work on other pharmaceutical industry litigation (such as the AWP MDL), this Court is intimately familiar with the pharmaceutical industry and the legal issues germane to it;
- Plaintiffs’ counsel in this action is also plaintiffs’ counsel in the *Neurontin Action*; and
- On Friday, April 7, 2006, Plaintiffs’ counsel filed *Francis v. Serono Laboratories, Inc, et al* C.A. No. 06- 10613 (PBS), which was assigned to this Court and purports to be another class action on behalf of purchasers of Serostim. That case pleads essentially the same claims as this action, and is based on the same allegedly improper sales and marketing practices involving Serostim.

¹ The only substantive difference is that there are no product liability claims in this case.

These factors provide this Court with particular expertise in the legal and factual issues that have arisen – and will arise – in this litigation, and the overlap of Plaintiffs’ counsel also puts the Court in a position to better deal with any scheduling issues that may arise. Finally, should the Plaintiffs decide to re-plead their AWP claims at some point, the Court will be able to quickly and easily fold this matter back into the AWP MDL with nothing being lost. These factors weigh heavily in favor of this Court keeping this action once it is unbundled from the AWP MDL, and Serono respectfully requests that it do so.

Under Local Rule 40(I) (Reassignment and Transfer of Cases) this Court “may transfer the case to another judge, if the other judge consents to the transfer.” In their Motion, Plaintiffs set forth a number of actions which involve – to varying degrees – aspects of what is alleged in this action and what is set forth in the Felony Information.² For purposes of completeness, and to provide this Court with the full range of options should it choose to transfer the case, Serono points out that there are two *qui tam* action before Judge O’Toole at this time, styled as *U.S. Ex Rel. Christine Driscoll v. Serono Laboratories, Inc.*, C.A. No. 00-11680 GAO and *U.S. Ex. Rel. Garcia v. Serono, Inc.* C.A. No. 03-11892 GAO. That Court would therefore provide another possible forum for this action under Local Rule 40(I), should this Court decide that a transfer is appropriate.

² In their papers, the Plaintiffs cite to the Annotated Manual for Complex Litigation Fourth (2004) § 10.123, at 20, for the proposition that “[a]ssignment of related criminal and civil cases to a single judge will improve efficiency and coordination, especially when the cases are pending at the same time” and suggest that this principle “may still obtain” for the Sentencing Court. For the reasons set forth earlier, Serono does not believe that is the case. The criminal action – *United States v. Serono Laboratories, Inc.* – is no longer pending, and was disposed of in a relatively rapid fashion. Therefore, there is nothing to coordinate, and the Sentencing Court will bring no additional efficiency or particular expertise to this matter. Consequently, assignment to the Sentencing Court will not necessarily be “in the interest of justice or to further the efficient performance of the business of the court” as set forth in Local Rule 40(I).

CONCLUSION

For the reasons set forth above, Serono respectfully requests that this Court “unbundle” this case from the AWP MDL, and continue to retain jurisdiction over it as Case No. 05-CV-11935 (PBS). In the alternative, Serono suggests that it would be appropriate to transfer this matter to the Court presiding over the aforementioned *qui tam* actions.

Respectfully submitted,

SERONO, INC.

By its attorneys,

/s/ David M. Ryan

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Dated: April 10, 2006

CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the above document to be served upon the attorney of record for each other party electronically on April 10, 2006.

/s/ David M. Ryan
